IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OSMOTICA PHARMACEUTICAL US LLC, and VERTICAL PHARMACEUTICALS, LLC, *Plaintiffs*, v. ADAMAS PHARMACEUTICALS, INC., and ADAMAS PHARMA, LLC *Defendants*.	Civil Action No. _____ JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT OF NONINFRINGEMENT

Plaintiffs Osmotica Pharmaceutical US LLC ("Osmotica US") and Vertical Pharmaceuticals, LLC ("Vertical") (collectively, "Osmotica") hereby bring this action against Defendants Adamas Pharmaceuticals, Inc. and Adamas Pharma, LLC (collectively, "Adamas") seeking a declaration that Osmotica has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent Nos. 8,389,578 ("the '578 patent"); 8,741,343 ("the '343 patent"); 8,796,337 ("the '337 patent"); 8,889,740 ("the '740 patent"); 8,895,614 ("the '614 patent"); 8,895,615 ("the '615 patent"); 8,895,616 ("the '616 patent"); 8,895,617 ("the '617 patent"); 8,895,618 ("the '618 patent"); 8,987,333 ("the '333 patent); and 9,072,697 ("the '697 patent") (collectively, the "patents-in-suits").

Osmotica brings this suit to obtain patent certainty as it stands ready to commercially launch its innovative and proprietary treatment for Parkinson's disease ("PD"), Osmolex ER™ tablets, which received approval for marketing from the U.S. Food and Drug Administration ("FDA") on February 16, 2018. *See* Exhibit O. By way of letter (Exhibit A) dated June 1, 2015,

Adamas actively and expressly communicated a threat to bring an action against Osmotica, alleging infringement of the patents-in-suit upon commercialization of Osmolex ER™. Adamas's affirmative conduct has created reasonable apprehension of litigation on the part of Osmotica, impeding Osmotica's plans and casting a cloud of uncertainty over the launch of its highly anticipated PD treatment. Osmotica therefore seeks relief in the form of a declaratory judgment of noninfringement of the patents-in-suit, which will allow Osmotica to provide Osmolex ER™ to the public as soon as possible—and free from the uncertainty of Adamas's lingering threat of litigation.

NATURE AND SUMMARY OF THIS ACTION

1. Plaintiff Osmotica US is an internationally recognized pharmaceutical company headquartered in Marietta, Georgia and is a world leader in osmotic drug delivery technology. Plaintiff Vertical, an affiliate of Osmotica US, is a specialty pharmaceutical company that, among other things, markets and distributes branded prescription drug products in the U.S. By leveraging significant resources in research and development and its various proprietary technologies, Osmotica has successfully developed and commercialized numerous high-quality branded and generic pharmaceutical products to address the growing need of the global patient population.

2. Upon information and belief, Defendant Adamas was founded in 2004 and has described itself as an "emerging" pharmaceutical company that develops "chrono-synchronous therapies" for the treatment of chronic neurologic disorders.

3. Both Osmotica and Adamas, along with a number of additional branded and generic companies, are involved in the development and commercialization of drug products,

including amantadine hydrochloride ("HCl") products, for use in a variety of different indications and administrations.

4. Pertinent to this case, Osmotica recently received FDA approval for its amantadine HCl product, uniquely formulated as an immediate-release *and* extended-release (*i.e.*, "IR/ER") combination tablet, indicated for, among other things, the treatment of PD.

5. Adamas previously received FDA approval for a different amantadine HCl drug product—extended-release-only capsules—which Adamas now markets in the U.S. under the trade name "Gocovri™." The FDA approved Gocovri™ for an indication entirely different from Osmotica's approved indication. Gocovri™ is indicated for the treatment of a side-effect known as levodopa-induced dyskinesia ("LID"): specifically, "the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications."

6. Upon its approval, Gocovri™ received an orphan-drug designation and related exclusivity for its approved LID indication. Gocovri™'s orphan exclusivity gives Adamas seven years of non-patent marketing exclusivity that prevents the FDA from approving another company's application "for the same drug for the same disease or condition" through August 24, 2024. *See, e.g.*, 21 U.S.C. § 360cc(a).

7. With the number of PD diagnoses growing each year, Osmotica set out to improve upon an existing PD treatment and submitted a New Drug Application ("NDA") to the FDA under 21 U.S.C. § 355(b)(2) for its innovative IR/ER dosage form. In support of its NDA, Osmotica relied, in part, on the FDA's previous finding of safety and effectiveness for amantadine HCl syrup, 50 mg/5 mL (Wockhardt, ANDA 075060). This amantadine HCl oral

syrup was previously marketed as "Symmetrel" by Endo (now discontinued[1]). The dose of the amantadine HCl oral syrup is expressed as amount of salt, *i.e.*, amantadine HCl.

8. There are critical differences that distinguish Osmotica's approved Osmolex ER™ product and Adamas's Gocovri™ product, which Adamas alleges to be the commercial embodiment of the patents-in-suit. For example, Osmotica's and Adamas's amantadine HCl products differ in at least six substantial respects.

- **Indications**: Osmolex ER™ is FDA-approved for treatment of PD and drug-induced extrapyramidal reactions in adult patients (similar to existing immediate-release amantadine HCl products), whereas Gocovri™ is FDA-approved for LID—which was the basis for Adamas's claims that Gocovri™ is special and deserving of orphan drug status and the related seven years of market exclusivity;

- **Timing of Administration**: Osmolex ER™ is dosed in the ***morning*** while Gocovri™ is dosed at ***bedtime***. Adamas alleges this bedtime dosing is a unique and novel feature claimed in a number of the patents-in-suit;

- **Dosage Form**: Osmolex ER™ is a ***tablet*** wherein the amantadine HCl is present as a combination of ***both*** immediate-release ***and*** extended-release amantadine HCl, while Gocovri™ is a ***capsule*** wherein all of the amantadine HCl is formulated into an extended-release form ***only***;

- **Dosage Strengths of Amantadine**:[2] 129 mg, 193 mg, and 258 mg for Osmolex ER™ versus 68.5 mg and 137 mg for Gocovri™;

- **Initial / Maximum Daily Dosages of Amantadine**: (Initial) 129 mg for Osmolex ER™ versus 137 mg for Gocovri™ / (Maximum) 322 mg for Osmolex ER™ versus 274 mg for Gocovri™; and

[1] "FDA has determined under [21 C.F.R.] § 314.161 that SYMMETREL (amantadine hydrochloride), Syrup, 50 mg/5 mL, was not withdrawn for reasons of safety or effectiveness. . . . Additional [applications] that refer to SYMMETREL (amantadine hydrochloride), Syrup, 50 mg/5 mL, may be approved by the Agency as long as they meet all other legal and regulatory requirements . . . ." 82 Fed. Reg. 5580, 5581 (Jan. 18, 2017).

[2] The dosage strengths are reported on the labels of both Osmolex ER™ and Gocovri™ in terms of the amantadine base. These values can be converted and reported in terms of the hydrochloride salt of amantadine, *i.e.*, amantadine HCl. For example, regarding Osmolex ER™, 129 mg, 193 mg, and 258 mg of amantadine base equates to 160 mg, 240 mg, and 320 mg amantadine HCl, respectively.

- **Inactive Ingredients**.

9. Despite these differences, Adamas has threatened to bring suit against Osmotica, alleging infringement of the patents-in-suit upon Osmotica's commercialization of its Osmolex ER™ product.

10. On the verge of launching its Osmolex ER™ product, Osmotica has expended significant resources, time, and effort on developing and securing regulatory approval for the product so that Osmotica can offer patients suffering from PD an innovative therapeutic option that is unique among existing amantadine products.

11. Osmotica therefore seeks relief in the form of a declaratory judgment of noninfringement of the patents-in-suit to remove the cloud of uncertainty created by Adamas.

THE PARTIES

12. Osmotica is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 895 Sawyer Road, Marietta, Georgia 30062.

13. Vertical Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey 08807.

14. Upon information and belief, Adamas Pharmaceuticals, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608.

15. Upon information and belief, Adamas Pharma, LLC, is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 1900 Powell Street, Suite 750, Emeryville, California 94608.

JURISDICTION AND VENUE

16. This is a civil action arising under the Patent Act, Title 35 of the United States Code, for a declaratory judgment of patent noninfringement under 28 U.S.C. §§ 2201 and 2202.

17. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq*.), as well as under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) because this action involves an actual case or controversy concerning the noninfringement of the patents-in-suit. *See* 28 U.S.C. § 2201(a) ("In a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.").

18. An actual case or controversy exists between Osmotica and Adamas because, under all of the circumstances, this action involves a definite and concrete dispute between parties having adverse legal interests. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

19. In particular, and as explained in further detail herein, Adamas's affirmative acts taken in connection with its June 1, 2015 letter to Osmotica establish a case or controversy because they, *inter alia*, have created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the patents-in-suit. *See Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1358, n.5 (Fed. Cir. 2013) ("While a declaratory judgment plaintiff is no longer required to demonstrate a reasonable apprehension of suit, such a showing remains sufficient to establish jurisdiction." (internal citations omitted)); *see also ScanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) ("[D]eclaratory judgment

jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do.").

20. Adamas's overt threat of litigation predicated upon the launch of Osmotica's Osmolex ER™ product (*See* Exhibit A at 2) establishes a case or controversy for purposes of declaratory judgment jurisdiction. And, even assuming *arguendo* that Adamas's June 1, 2015 letter does not represent a sufficient threat of litigation, that letter still provides a basis for declaratory-judgment jurisdiction. *See, e.g.*, *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330 (Fed. Cir. 2014) ("[T]he Supreme Court has repeatedly found the existence of an actual case or controversy even in situations in which there was no indication that the declaratory judgment defendant was preparing to enforce its legal rights."); *see also ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) ("A specific threat of infringement litigation by the patentee is not required to establish jurisdiction."); *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358, 1362 (Fed. Cir. 2009) ("The purpose of a declaratory judgment action cannot be defeated simply by the stratagem of a correspondence that avoids the magic words such as 'litigation' or 'infringement.'").

21. Now that Osmotica has received final FDA-approval clearing the way to launch its Osmolex ER™ product, an actual case or controversy exists. *See Arkema Inc. v. Honeywell Int'l Inc.*, 706 F.3d 1351, 1359-60 (Fed. Cir. 2013).

22. With the long-expected approval date of Osmotica's Osmolex ER™ product now here, Adamas's conduct has caused Osmotica to face "the choice between abandoning [its] rights

or risking prosecution," further confirming declaratory judgment jurisdiction. *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 129 (2007); *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007) ("Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do.").

23. The Court has personal jurisdiction over Adamas Pharmaceuticals, Inc., and Adamas Pharma, LLC, because, among other reasons, on information and belief, both entities are currently incorporated in the State of Delaware (File Nos. 3305590 and 6404360, respectively) and have been since November 15, 2000, and May 8, 2017, respectively. On information and belief, Adamas Pharmaceuticals, Inc., and Adamas Pharma, LLC, have also designated their registered agents for service of process in the State of Delaware as "The Prentice-Hall Corporation System, Inc.," 251 Little Falls Drive, Wilmington, Delaware 19808, and "Corporation Service Company," 251 Little Falls Drive, Wilmington, Delaware 19808, respectively.

24. On information and belief, this Court also has personal jurisdiction over Adamas because of Adamas's continuous and systematic contacts with the State of Delaware, including the substantial and regular business conducted by Adamas therein through marketing and sales of pharmaceutical products in the State of Delaware. Further, Adamas has previously subjected itself to the jurisdiction of this Court for purposes of litigating its patent disputes (*e.g.*, in 1-16-cv-01045; 1-16-cv-00917; 1-16-cv-00375).

25. Venue in this judicial district is proper under 28 U.S.C. §1391(b) and (c) at least because both Adamas Pharmaceuticals, Inc., and Adamas Pharma, LLC, are incorporated in the State of Delaware and both are subject to this Court's personal jurisdiction.

26. A real, immediate, substantial, and justiciable controversy exists between Osmotica and Adamas with respect to the question of infringement of the patents-in-suit.

THE PATENTS-IN-SUIT

A. The ’578 Patent

27. The ’578 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 11/286,448 (“the ’448 application”) on March 5, 2013. The ’448 application was filed on November 23, 2005, and claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

28. The ’578 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’578 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’578 patent.

29. A copy of the ’578 patent is attached hereto as Exhibit B.

B. The ’343 Patent

30. The ’343 patent, titled “Method of Administering Amantadine Prior to a Sleep Period,” issued from U.S. Patent Application No. 12/959,321 (“the ’321 application”) on June 3, 2014. The ’321 application was filed December 2, 2010, and claims benefit to U.S. Provisional Patent Application No. 61/266,053, filed December 2, 2009.

31. The ’343 patent lists Gregory T. Went, Gayatri Sathyan, Kavita Vermani, Gangadhara Ganapati, Michael Coffee, Efraim Shek, and Ashok Katdare as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’343 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’343 patent.

32. A copy of the ’343 patent is attached hereto as Exhibit C.

C. The ’337 Patent

33. The ’337 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 13/958,153 (“the ’153 application”) on August 5, 2014. The ’153 application was filed August 2, 2013, and is a continuation application of U.S. Patent Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of U.S. Patent Application No. 11/286,448, filed November 23, 2005, now U.S. Pat. No. 8,389,578, which claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

34. The ’337 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’337 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’337 patent.

35. A copy of the ’337 patent is attached hereto as Exhibit D.

D. The ’740 Patent

36. The ’740 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,250 (“the ’250 application”) on November 18, 2014. The ’250 application was a continuation of Application No. 14/328,440, filed on July 10, 2014, now, U.S. Patent No. 8,895,614, which is a continuation of application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims the benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

37. The ’740 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’740 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’740 patent.

38. A copy of the ’740 patent is attached hereto as Exhibit E.

E. The ’614 Patent

39. The ’614 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/328,440 (“the ’440 application”) on November 25, 2014. The ’440 application was filed on July 10, 2014, which is a continuation of application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims the benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

40. The ’614 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’614 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’614 patent.

41. A copy of copy of the ’614 patent is attached hereto as Exhibit F.

F. The ’615 Patent

42. The ’615 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,226 (“the ’226 application”) on November 25, 2014. The ’226 application, filed on August 4, 2014, is a continuation of Application No. 14/328,440, filed on July 10, 2014, now U.S. Patent No. 8,895,614, which is a

continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

43. The ’615 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’615 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’615 patent.

44. A copy of the ’615 patent is attached hereto as Exhibit G.

G. The ’616 Patent

45. The ’616 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,242 (“the ’242 application”) on November 25, 2014. The ’242 application, filed on August 4, 2014, is a continuation of Application No. 14/328,440, now U.S. Patent No. 8,895,614, filed on July 10, 2014, which is a continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

46. The ’616 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’616 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’616 patent.

47. A copy of the ’616 patent is attached hereto as Exhibit H.

H. The ’617 Patent

48. The ’617 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,273 (“the ’273 application”) on November 25, 2014. The ’273 application, filed on August 4, 2014, is a continuation of Application No. 14/328,440, now U.S. Patent No. 8,895,614, filed on July 10, 2014, which is a continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

49. The ’617 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’617 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’617 patent.

50. A copy of the ’617 patent is attached hereto as Exhibit I.

I. The ’618 Patent

51. The ’618 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,282 (“the ’282 application”) on November 25, 2014. The ’282 application, filed on August 4, 2014, is a continuation of Application No. 14/328,440, filed on July 10, 2014, now U.S. Patent No. 8,895,614, which is a continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005,

now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

52. The ’618 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’618 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’618 patent.

53. A copy of the ’618 patent is attached hereto as Exhibit J.

J. The ’333 Patent

54. The ’333 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/451,262 (“the ’262 application”) on March 24, 2015. The ’262 application, filed on August 4, 2014, is a continuation of Application No. 14/328,440, filed on July 10, 2014, now U.S. Patent No. 8,895,614, which is a continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

55. The ’333 patent lists Gregory T. Went, Timothy J. Fultz, Seth Porter, Laurence R. Meyerson, and Timothy S. Burkoth as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’333 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’333 patent.

56. A copy of the ’333 patent is attached hereto as Exhibit K.

K. The ’697 Patent

57. The ’697 patent, titled “Composition and Method for Treating Neurological Disease,” issued from U.S. Patent Application No. 14/591,641 (“the ’641 application”) on July 7, 2015. The ’541 application, filed on January 7, 2015, is a continuation of Application No. 14/451,262, filed on August 4, 2014, now U.S. Patent No. 8,987, 333, which is a continuation of Application No. 14/328,440, filed on July 10, 2014, now U.S. Patent No. 8,895,614, which is a continuation of Application No. 13/958,153, filed on August 2, 2013, now U.S. Patent No. 8,796,337, which is a continuation of Application No. 13/756,275, filed on January 31, 2013, abandoned, which is a continuation of Application No. 11/286,448, filed on November 23, 2005, now U.S. Patent No. 8,389,578. The ’578 patent claims benefit to U.S. Provisional Patent Application No. 60/631,095, filed November 24, 2004.

58. The ’697 patent lists Gregory T. Went and Timothy J. Fultz as the inventors. On information and belief, Adamas Pharma, LLC, is the current assignee of the ’697 patent, and Adamas Pharmaceuticals, Inc., was the original assignee of the ’697 patent.

59. A copy of the ’697 patent is attached hereto as Exhibit L.

FACTUAL BACKGROUND

A. Statutory Framework

60. The Federal Food, Drug, and Cosmetics Act (“Act”) governs the FDA’s approval of pharmaceutical drug products. *See* 21 U.S.C. § 355 *et seq*. The Act and its amendments require drug manufacturers seeking to market a new drug to first obtain FDA approval using one of three different application pathways: (1) a full NDA; (2) an Abbreviated New Drug Application (“ANDA”); or (3) an intermediate process known as a Section 505(b)(2) NDA. *See*

21 U.S.C. § 355; *see also, e.g.*, *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 226-27 (3d Cir. 2013) (describing the three different approval methods).

61. The full NDA process requires the drug manufacturer to submit detailed safety and efficacy data for the drug, including, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use" (*i.e.*, clinical trials); all components of the drug; the methods used for the drug's manufacture, processing, and packing; examples for proposed labeling for the drug; and any patents claimed in relation to the drug. *See* 21 U.S.C. §§ 355(b)(1)(A), (B), (D), (F), (G). This path is used by drug manufacturers for "new branded drug[s]," *Ethypharm S.A. France*, 707 F.3d at 226, which are sometimes called "pioneer" or "innovator" drugs.

62. A drug manufacturer may also choose to file an ANDA pursuant to 21 U.S.C. § 355(j). The ANDA process facilitates efficient approval of generic versions of branded drug products that have already been determined to be safe and effective. Rather than requiring a generic manufacturer to conduct expensive and time consuming clinical trials, the ANDA process allows the manufacturer to rely on the clinical trials already performed in connection with the approval of a previously approved drug, provided that the generic manufacturer can show that its drug has the same relevant characteristics (including, *inter alia*, labeling, active ingredient, route of administration, dosage form, strength, and bioequivalence). *See* 21 U.S.C. § 355(j)(2)(A). In other words, an ANDA does not attempt to demonstrate safety or effectiveness; instead, an ANDA applicant's goal is to establish that the generic product is bioequivalent to another drug that is already known to be safe and effective. Thus, this path is used by drug manufacturers "for the introduction of generic versions of previously approved branded drugs." *Ethypharm S.A. France*, 707 F.3d at 227.

63. A section 505(b)(2) NDA can be fairly described as a hybrid of the full NDA and ANDA pathways. Like the full NDA, a 505(b)(2) NDA must directly demonstrate that the proposed drug product is safe and effective; however, like the ANDA, a 505(b)(2) applicant can rely on preclinical and clinical studies that were previously submitted to FDA in support of another drug and that were not conducted or licensed by the 505(b)(2) applicant. *See* 21 U.S.C. § 355(b)(2). The drug for which the borrowed studies were conducted is referred to as the reference drug, and the reference drug's clinical studies that a Section 505(b)(2) applicant relies upon may be proffered to satisfy the applicant's entire burden of proving safety and effectiveness, or they may only support some of the necessary findings; in the latter case, the applicant can supplement with studies of its own. This means that a section 505(b)(2) NDA may include the applicant's own research supporting the safety and efficacy of the drug in addition to the research studies related to the reference drug, or it may rely entirely on the reference drug. In any event, a section 505(b)(2) applicant must present information that bears upon the safety and effectiveness of its drug product in light of the difference between the reference drug and the applicant's modification of that drug product. The 505(b)(2) NDA pathway is often used when the new drug differs slightly from the reference drug, including differences in route of administration, dosage form, dosage strength, etc. This pathway is often favored by drug manufacturers seeking to market drugs that are neither "entirely new" nor "simply a generic version of a branded drug." *Ethypharm S.A. France*, 707 F.3d at 227.

64. Relatedly, Congress gives pharmaceutical companies different periods of market exclusivity, depending in part on the type of drug they develop. *See, e.g.*, 21 U.S.C. § 355(a)-(j). When the potential market for a drug is small because of a relatively small targeted patient population, it is difficult for a pharmaceutical company to recover its research and development

costs and realize a worthwhile return on investment. In 1983, Congress passed the Orphan Drug Act (21 U.S.C. §§ 360aa-ee) to provide pharmaceutical companies with an incentive to develop and test drugs for the treatment of "rare diseases or conditions," which is defined to include diseases or conditions affecting fewer than 200,000 people in the United States. *See* 21 U.S.C. § 360bb(2)(A).

65. Obtaining "orphan drug" status provides incentives to the manufacturer in the form of tax breaks, assistance from the FDA in studying the drug, and, most importantly, seven years of non-patent marketing exclusivity. *See* 21 U.S.C. § 360cc(a). The Orphan Drug Act provides that once the FDA approves a drug "designated . . . for a rare disease or condition," it may not approve another application "for the same drug for the same disease or condition" by another company for seven years. *See* 21 U.S.C. § 360cc(a).

B. Background of PD

66. PD is a chronic and progressive neurodegenerative disorder that can cause tremors, slowness of movements, limb rigidity, as well as gait and balance problems. PD is one of the most common age-related neurodegenerative disorders, second in frequency only to Alzheimer's disease.

67. Even as early as 2001, at least half a million people in the U.S. were diagnosed with PD, and that number has grown steadily since. In addition, the frequency of PD is predicted to triple over the next 50 years as the average age of the population increases. As of 2011, it was estimated that there were approximately one million people living with PD in the U.S., with another 60,000 diagnosed each year.

68. The disease itself is not fatal, but the complications caused by PD are the 14th leading cause of death in the U.S. The average age of diagnosis is around 60, but approximately 15% of people with PD are diagnosed before age 50 and are said to have young-onset PD.

69. Although there is currently no cure for PD, there are several measures that can be taken to improve a patient's quality of life, including drug therapies to treat the underlying condition of PD as well as common side-effects associated with the disease.

70. Both Osmotica and Adamas, along with many other branded and generic companies, have been involved in the research and development of therapies relating to the treatment of PD and its various complications.

1. *Levodopa-based Therapies*

71. Historically, the most commonly prescribed treatments for PD are levodopa-based therapies. In the human body, levodopa (also known as "L-dopa"), is converted to dopamine to replace the dopamine loss caused by PD. Patients initially receive relief from symptoms of PD for much of the day; this period of relief is known as "ON" time. As the therapeutic effects of L-dopa wear off, the symptoms of PD return; this is known as "OFF" time.

72. L-dopa is often combined with the drug carbidopa, which protects levodopa from premature conversion to dopamine outside of a patient's brain, preventing or lessening side-effects such as nausea.

73. As PD progresses over time, most patients require increasing doses of L-dopa to achieve equivalent therapeutic benefit. But even with increased doses of L-dopa, as PD continues to progress the benefits of L-dopa-based treatments may become less stable and have a tendency to wax and wane.

2. *Amantadine HCl Therapies*

74. Amantadine HCl has been used to treat PD. Amantadine HCl, originally approved for the prophylaxis of influenza A virus in 1966, was discovered as a treatment of, among other things, parkinsonism in 1969. Parkinsonism is a general term that refers to a group of

neurological disorders that cause movement problems similar to those seen in PD, such as tremors, slow movement, and stiffness.

75. By 2003, at least 17 robust randomized, double-blind crossover trials had been published on the use of amantadine HCl for control of PD. This led to the approval by the FDA in 2003 of two immediate-release dosage forms of amantadine HCl—syrup and tablets—for the treatment of, *inter alia*, parkinsonism. These immediate-release dosage forms of amantadine HCl were marketed under the brand name "Symmetrel." *See* Exhibit M.

3. *Therapies for the Side Effects of Levodopa-based Therapies*

76. It was known that patients on long-term L-dopa therapy may experience a side-effect known as LID. LID is characterized by involuntary, non-purposeful movements of the head and neck, arms, legs or trunk of a patient receiving L-dopa therapy.

77. LID affects approximately 30% of patients taking L-dopa and is particularly problematic among young-onset PD patients.

78. As of June 2013, there were no medications approved for the treatment of LID.

C. Background of Drug-Induced Extrapyramidal Reactions

79. In addition to treating PD and LID, amantadine HCl has been shown to be effective in treating a separate and distinct disorder known as drug-induced extrapyramidal reactions (also referred to as drug-induced extrapyramidal symptoms or drug-induced extrapyramidal side effects).

80. Drug-induced extrapyramidal reactions are drug-induced movement disorders that include acute and tardive symptoms caused by the administration of several different types of drugs such as antipsychotics, neuroleptic agents, antiemetics, and antidepressants. Such symptoms include dystonia (continuous spasms and muscle contractions), akathisia (motor

restlessness), parkinsonism (characteristic symptoms such as rigidity), bradykinesia (slowness of movement), tremor, and tardive dyskinesia (irregular, jerky, movements).

81. Drug-induced extrapyramidal reactions may be caused by various different drugs: for example, antipsychotics, such as haloperidol, fluphenazine, thiothixene, trifluoroperazine, acetophenazine, prochlorperazine, perphenazine, loxapine, chlorpromazine, triflupromazine, molindone, mesoridazine, chlorprothixene, thioridazine, clozapine; antiemetics and other anti-dopaminergic drugs, such as antiemetic metoclopramide, trimethobenzamide (*e.g.*, Tigan®) and metoclopramide (*e.g.*, Reglan®); antidepressants, such as selective serotonin reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake inhibitors (SNRI), and norepinephrine-dopamine reuptake inhibitors (NDRI), desipramine (*e.g.*, Norpramin®), protriptyline (*e.g.*, Vivactil®), duloxetine, sertraline, escitalopram, fluoxetine, and bupropion; anticonvulsant agents such as phenytoin (*e.g.*, Dilantin®) and carbamazepine (*e.g.*, Tegretol®); other substituted benzamides; concomitantly using neuroleptic agents and lithium; and oral contraceptives.

82. Immediate-release amantadine HCl products have previously been indicated and used for the treatment of drug-induced extrapyramidal reactions. *See, e.g.*, Exhibit M. Osmotica's Osmolex ER™ product is FDA-approved for the treatment of drug-induced extrapyramidal reactions, while Adamas's Gocovri™ product is not FDA approved for that indication.

D. Osmotica's Osmolex ER™ Amantadine Product

83. Osmotica has made substantial investments in the development of Osmolex ER™. Research and development efforts date back to 2008. Since that time, Osmotica has invested millions of dollars to bring Osmolex ER™ to market.

84. Osmolex ER™ is formulated as a single tablet containing a combination of immediate-release and extended-release amantadine HCl as its active pharmaceutical ingredient.

85. Osmolex ER™ is approved for and available in three strengths: 129 mg, 193 mg, and 258 mg (expressed as amantadine base).

86. Similar to generic amantadine HCl products that are already available, the FDA has approved Osmolex ER™ for the treatment of: (1) Parkinson's disease; and (2) drug-induced extrapyramidal reactions in adult patients. *See* Exhibit N.

87. The Dosage and Administration section of the FDA-approved Osmolex ER™ product label states, among other things, that: "The recommended initial dosage of OSMOLEX ER is 129 mg administered orally once daily in the morning. The dosage may be increased in weekly intervals to a maximum daily dose of 320 mg (administered as a 129 mg and 193 mg tablet), taken in the morning." *See* Exhibit N.

88. Osmotica US received Final FDA-approval for Osmolex ER™ on February 16, 2018. *See* Exhibit O. Osmotica US, together with its branded-division Vertical, seek to bring Osmolex ER™ to market in the second quarter of 2018.

89. Osmotica US developed Osmolex ER™ and obtained FDA approval through the 505(b)(2) regulatory pathway, relying, in part, on the FDA's previous finding of safety and effectiveness for amantadine HCl syrup, 50 mg/5 mL (Wockhardt, ANDA 075060). The reference listed drug relied upon in Wockhardt's ANDA No. 075060 was Symmetrel (amantadine HCl syrup, 50 mg/5 mL).

90. In support of its 505(b)(2) application, Osmotica US submitted data from three of its own bioavailability studies, which were conducted in healthy volunteers to bridge to amantadine HCl syrup, 50 mg/5 mL and establish the safety and efficacy of Osmolex ER™. *See* Exhibit N.

91. As required by the FDA, the approved Osmolex ER™ product label is substantially similar to the approved label for Symmetrel. *Compare* Exhibit M *with* Exhibit N.

92. Upon information and belief, Symmetrel was the subject of NDA Nos. 016023 and 017118, held by Endo Pharmaceuticals, and initially approved on February 14, 1968, and July 20, 1976, respectively.

93. Symmetrel was indicated for the treatment of parkinsonism and drug-induced extrapyramidal reactions.

E. Adamas's Amantadine HCl Product

94. Upon information and belief, by around 2009, there were no FDA-approved drug products specifically indicated for the treatment of LID in patients with PD.

95. Upon information and belief, during or before 2009, Adamas began developing an investigational drug product referred to at the time as "ADS-5102," specifically targeting treatment of LID in patients with PD.

96. Upon information and belief, Adamas has described its ADS-5102 product as "amantadine . . . for the treatment of LID."

97. On information and belief, Adamas formulated its ADS-5102 product as a once-daily, ***extended-release only*** capsule formulation intended for ***night-time administration***, having amantadine HCl as the active pharmaceutical ingredient.

98. Upon information and belief, on or around September 28, 2011, Adamas announced that it had initiated a Phase 2/3 clinical trial of ADS-5102.

99. Upon information and belief, Adamas has referred to the Phase 2/3 clinical trial of ADS-5102 as "Extended Release Amantadine Safety and Efficacy Study in Levodopa-Induced Dyskinesia (EASED Study)."

100. Upon information and belief, Adamas designed the EASED Study to investigate the ADS-5102 drug product's efficacy in treating the side effects associated with the administration of levodopa as a course of treatment for PD patients.

101. Upon information and belief, by June of 2012, Adamas referred to the ADS-5102 product as either "ADS-5102" or "Nurelin,™," or both.

102. Upon information and belief, by or around April 30, 2014, Adamas ceased referring to the ADS-5102 product as "Nurelin™."

103. Upon information and belief, on or around April 30, 2014, Adamas announced its intention to commence a Phase 3 study related to ADS-5102 with a "primary objective" of confirming "the efficacy of a once-nightly 340 mg dose of ADS-5102 for the treatment of LID in subjects" with PD.

104. Upon information and belief, in an October 28, 2014 press release, Adamas announced the initiation of an additional Phase 3 safety and efficacy study evaluating ADS-5102 for the treatment of LID in patients with PD. In that press release, Adamas described ADS-5102 as "a high dose, controlled-release version of amantadine HCl administered once daily at bedtime."

105. Upon information and belief, on or around April 10, 2015, the FDA indicated that ADS-5102 would be granted orphan drug designation which, upon approval, would confer the related seven-year exclusivity specifically and exclusively for the treatment of LID in patients suffering from PD, as requested by Adamas.

106. Upon information and belief, on or about October 24, 2016, Adamas submitted its NDA No. 208944 to the FDA for ADS-5102 (amantadine HCl) extended-release capsules, pursuant to section 505(b)(2) of the Act.

107. Upon information and belief, to support its submission to the FDA of NDA No. 208944, Adamas included data from various clinical trials that Adamas referred to as "EASED," "EASE LID," "EASE LID 2," and "EASED LID 3."

108. Upon information and belief, on or about January 6, 2017, the FDA accepted for review Adamas's NDA No. 208944 for ADS-5102 (amantadine HCl) extended-release capsules, for the treatment of LID in patients undergoing levodopa treatment for PD.

109. Upon information and belief, the FDA gave NDA No. 208944 a Prescription Drug User Fee Act target action date of August 24, 2017.

110. Upon information and belief, on or about August 24, 2017, Adamas received approval from the FDA to launch extended-release capsules to be marketed under the proprietary name Gocovri™, indicated solely and exclusively "for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications."

111. Upon information and belief, on or around October 25, 2017, the FDA granted Adamas's Gocovri™ product orphan drug exclusivity for the treatment of LID in PD patients.

112. Upon information and belief, the orphan drug designation awarded to Adamas for Gocovri™ means that Adamas will enjoy complete exclusivity for the LID indication for seven years from its date of approval. As a result, only after August 24, 2024, will another amantadine HCl product be permitted to enter the market carrying the LID indication.

113. Upon information and belief, had Adamas received other indications for Gocovri™, which were not the beneficiary of orphan drug designation and exclusivity, then that would open the door for early competition by generics in advance of the seven-year orphan exclusivity period for such other indications.

114. Upon information and belief, Adamas sought, obtained, and limited the indications for Gocovri™ to LID as a means to forestall generic competition, and corner the market for Gocovri™ and LID treatment.

115. Upon information and belief, Adamas included the following patents in the Orange Book listing for NDA No. 208944: the ’578 patent (Exhibit B); the ’343 patent (Exhibit C); the ’337 patent (Exhibit D); the ’740 patent (Exhibit E); “the ’614 patent (Exhibit F); the ’615 patent (Exhibit G); the ’616 patent (Exhibit H); the ’617 patent (Exhibit I); the ’618 patent (Exhibit J); and U.S. Patent Nos. 9,867,791; 9,867,792; and 9,867,793.

116. Upon information and belief, with the exception of the ’343 patent, every other patent-in-suit claims priority to U.S. Provisional Application No. 60/631,095, and each includes a functional limitation: specifically, the administration of an amantadine extended-release formulation that accomplishes a particular change in plasma concentrations as a function of time (dC/dT).

117. Upon information and belief, the ’343 patent claims priority to U.S. Provisional Application No. 61/266,053 and covers only the administration of an amantadine, in extended-release form only, “once daily 0 to 4 hours before bedtime.”

F. Acts Leading to the Present Dispute

118. On January 18, 2017, Osmotica US submitted a 505(b)(2) application to FDA, seeking approval of amantadine extended-release (with an immediate-release component) tablets in the following dosage strengths: 129 mg, 193 mg, and 258 mg (160 mg, 240 mg, and 320 mg amantadine HCl). Osmotica US’s 505(b)(2) application includes data from comparative bioavailability studies. The approved immediate-release product used as the reference standard in Osmotica US’s bioavailability studies was amantadine HCl syrup, 50 mg/5 mL (Wockhardt, ANDA No. 075060).

119. Osmotica US's application notably did not seek approval of its amantadine HCl IR/ER tablet product for the treatment of LID.

120. On June 1, 2015, after learning of Osmotica's development program through publicly available information, Adamas sent a threatening letter (Exhibit A) to Osmotica regarding its research and development stating, in pertinent part, the following:

> [W]e believe that the commercialization of your planned product must consider [Adamas's] intellectual property. We believe that the manufacture and sale of many extended-release amantadine products of this type will result in infringement of one or more of our issued patents, and of claims we expect to issue in our pending applications. We expect to enforce our patents against products that infringe our intellectual property.

121. Adamas's June 1, 2015 letter was targeting what is now the approved Osmolex ER™ product, which Osmotica intends to bring to market, and which Osmotica submits does not infringe any valid and enforceable claim of the patents-in-suit.

CLAIMS FOR RELIEF

COUNT I: DECLARATION OF NON-INFRINGEMENT OF THE '578 PATENT

122. Osmotica expressly incorporates and realleges Paragraphs 1 through 121 above as if fully set out and stated herein.

123. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '578 patent.

124. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '578 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

125. The manufacture, use, offer for sale, sale, and/or importation of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to

the infringement by others of any valid and enforceable claim of the ’578 patent, either literally or under the doctrine of equivalents.

126. For example, claim 1 of the ’578 patent, which is representative, is directed to a method of treating a patient with PD comprising orally administering to the patient a first agent comprising a therapeutically effective amount of levodopa/carbidopa in an immediate-release form and a second agent consisting of 200 mg to 500 mg of amantadine in an extended-release form having a specific dC/dT profile. *See* Exhibit B, ’578 patent, 23:41-24:3. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the ’578 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

127. Additionally, Osmotica’s Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer solely contain amantadine HCl as the active agent. Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its approved product label will not satisfy at least the following limitations recited in claim 1 of the ’578 patent: “a first agent and . . . a second agent, said first agent comprising a therapeutically effective amount of levodopa/carbidopa in an immediate-release form and said second agent consisting essentially of a therapeutically effective amount of amantadine or pharmaceutically acceptable salt thereof in an amount ranging from 200 mg to 500 mg in extended release form.” Exhibit B, ’578 patent, 23:42-48. And to the extent that the first agent may also contain amantadine, the use of Osmotica’s Osmolex ER™ product in accordance with its approved product label also does not satisfy at least the following limitation recited in claim 1 of the ’578 patent: “said first agent comprising a therapeutically effective amount of levodopa/carbidopa.”

128. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’578 patent.

COUNT II: DECLARATION OF NON-INFRINGEMENT OF THE ’343 PATENT

129. Osmotica expressly incorporates and realleges Paragraphs 1 through 128 above as if fully set out and stated herein.

130. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the ’343 patent.

131. Adamas’s conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the ’343 patent, thereby impeding Osmotica’s ability to launch its Osmolex ER™ product without a cloud of uncertainty.

132. The importation, manufacture, offer to sell, sale, and/or use of Osmotica’s Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the ’343 patent, either literally or under the doctrine of equivalents.

133. For example, claim 1 of the ’343 patent, which is representative, is directed to a method of administering amantadine to a human subject 0 to 4 hours before bedtime. *See* Exhibit C, ’343 patent, 55:56-58. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the ’343 patent. *See Warner-Lambert v. Apotex,* 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

134. Additionally, the Dosage and Administration section of the approved Osmolex ER™ product label recommends dosing “in the morning.” Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its

approved product label will not satisfy at least the following limitation recited in claim 1 of the ’343 patent: “orally administering said composition once daily 0 to 4 hours before bedtime to a human subject.” Exhibit C, ’343 patent, 55:56-67.

135. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’343 patent.

COUNT III: DECLARATION OF NON-INFRINGEMENT OF THE ’337 PATENT

136. Osmotica expressly incorporates and realleges Paragraphs 1 through 135 above as if fully set out and stated herein.

137. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the ’337 patent.

138. Adamas’s conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the ’337 patent, thereby impeding Osmotica’s ability to launch its Osmolex ER™ product without a cloud of uncertainty.

139. The importation, manufacture, offer to sell, sale, and/or use of Osmotica’s Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the ’337 patent, either literally or under the doctrine of equivalents.

140. For example, claim 1 of the ’337 patent, which is representative, is directed to a method comprising, *inter alia*, orally administering to a human subject amantadine in a modified release pharmaceutical composition. *See* Exhibit D, ’337 patent, 22:39-56. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the ’337 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

141. Additionally, the dC/dT profile in the period of 0 and 4 hours after the administration of a dose of Osmotica's Osmolex ER™ product is greater than 40% of the dC/dT of the same quantity of an immediate-release form of amantadine over the same time period. Therefore, any use by third parties, including physicians and patients, of Osmotica's Osmolex ER™ product in accordance with its approved product label will not satisfy at least the following limitation recited in claim 1 of the '337 patent: "a dose of the composition provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by a dose of the same quantity of an immediate-release form of amantadine, wherein dC/dT is measured in a single dose human pharmacokinetic study in a defined time period of 0 to 4 hours after administration." Exhibit D, '337 patent, 22:39-56.

142. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '337 patent.

COUNT IV: DECLARATION OF NON-INFRINGEMENT OF THE '740 PATENT

143. Osmotica expressly incorporates and realleges Paragraphs 1 through 142 above as if fully set out and stated herein.

144. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '740 patent.

145. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '740 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

146. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe any valid and enforceable claim of the '740 patent, either literally or under the doctrine of equivalents.

147. For example, claim 1 of the '740 patent, which is representative, is directed to a dosage form consisting of 50 mg to 500 mg of amantadine or pharmaceutically acceptable salts thereof, wherein at least 50% of the drug in the dosage form is in the extended-release form, and the dosage form provides a mean change in amantadine plasma concentration as a function of time (dC/dT) as measured in a single dose human pharmacokinetic study over the time period between 2 hours and 4 hours after administration that is less than 30% of the dC/dT provided by the same quantity of the drug in an immediate-release form as measured in a single dose human pharmacokinetic study over the time period between 0 and 2 hours after administration. *See* Exhibit E, '740 patent, 23:9-22. Contextually, for example, when read in light of dependent claim 9, which requires that the dosage form "additionally comprises the drug in an immediate-release form," (Exhibit E, '740 patent, 24:20-21), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

148. Osmotica's Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent.

149. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not directly infringe any valid and enforceable claim of the '740 patent.

COUNT V: DECLARATION OF NON-INFRINGEMENT OF THE '614 PATENT

150. Osmotica expressly incorporates and realleges Paragraphs 1 through 149 above as if fully set out and stated herein.

151. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the ’614 patent.

152. Adamas’s conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the ’614 patent, thereby impeding Osmotica’s ability to launch its Osmolex ER™ product without a cloud of uncertainty.

153. The importation, manufacture, offer to sell, sale, and/or use of Osmotica’s Osmolex ER™ product has not, does not, and will not directly infringe any valid and enforceable claim of the ’614 patent, either literally or under the doctrine of equivalents.

154. For example, claim 1 of the ’614 patent, which is representative, is directed to a dosage form consisting of 50 mg to 500 mg of amantadine or pharmaceutically acceptable salts thereof, wherein at least 50% of the drug in the dosage form is in the extended-release form, and the dosage form provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of the drug in an immediate-release form as measured in a single dose human pharmacokinetic study over the time period between 0 and 4 hours after administration. Exhibit F, ’614 patent, 23:17-32. The dC/dT profile in the period of 0 and 4 hours after the administration of a dose of Osmotica’s Osmolex ER™ product is greater than 40% of the dC/dT of the same quantity of an immediate-release form of amantadine over the same time period. Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its approved product label will not satisfy at least the following limitation recited in claim 1 of the ’614 patent: “the dosage form provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of the drug in an immediate release form, wherein the dC/dT values are measured in a single dose

human pharmacokinetic study over the time period between 0 and 4 hours after administration." Exhibit F, '614 patent, 23:25-32.

155. In addition, contextually, for example, when read in view of dependent claim 11 of the '614 patent, which requires that the dosage form "additionally comprises the drug in an immediate-release form," (Exhibit F, '614 patent, 24:40-43), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

156. Osmotica's Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent.

157. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not directly infringe any valid and enforceable claim of the '614 patent.

COUNT VI: DECLARATION OF NON-INFRINGEMENT OF THE '615 PATENT

158. Osmotica expressly incorporates and realleges Paragraphs 1 through 157 above as if fully set out and stated herein.

159. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '615 patent.

160. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '615 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

161. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the '615 patent, either literally or under the doctrine of equivalents.

162. For example, claim 1 of the ’615 patent, which is representative, is directed to a method comprising, *inter alia*, orally administering to a human subject a once-daily dose consisting of 200 mg to 500 mg of amantadine. *See* Exhibit G, ’615 patent, 22:55-23:2. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the ’615 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

163. Additionally, claim 1 of the ’615 patent recites “a once-daily dose consisting of” amantadine or a pharmaceutically acceptable salt thereof and at least one excipient. Exhibit G, ’615 patent, 22:61-62. Contextually, for example, when read in view of dependent claim 6 of the ’615 patent, which requires that the dosage form “additionally comprises the drug in an immediate-release form,” (Exhibit G, ’615 patent, 24:5-6), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

164. Osmotica’s Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent. Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its approved product label will not satisfy the limitations of claim 1 of the ’615 patent.

165. Furthermore, the dC/dT profile in the period of 0 and 4 hours after the administration of a dose of Osmotica’s Osmolex ER™ product is greater than 40% of the dC/dT of the same quantity of an immediate-release form of amantadine over the same time period. Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its approved product label will not satisfy at least the following limitation recited in claim 1 of the ’615 patent: “wherein the dose provides a mean change in

amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of the drug in an immediate release form, wherein the dC/dT values are measured in a single dose human pharmacokinetic study over the time period between 0 and 4 hours after administration." Exhibit G, '615 patent, 22:63-23:2.

166. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '615 patent.

COUNT VII: DECLARATION OF NON-INFRINGEMENT OF THE '616 PATENT

167. Osmotica expressly incorporates and realleges Paragraphs 1 through 166 above as if fully set out and stated herein.

168. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '616 patent.

169. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '616 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

170. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the '616 patent, either literally or under the doctrine of equivalents.

171. For example, claim 1 of the '616 patent, which is representative, is directed to a method comprising, *inter alia*, orally administering to a human subject a once-daily dose consisting of 200 mg to 500 mg of amantadine. Exhibit H, '616 patent, 22:53-23:2. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly

infringe the ’616 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

172. Additionally, claim 1 of the ’616 patent recites “a once-daily dose consisting of” amantadine or a pharmaceutically acceptable salt thereof and at least one excipient. Exhibit H, ’616 patent, 22:56-59. Contextually, for example, when read in view of dependent claim 4 of the ’616 patent, which requires that the dosage form “additionally comprises the drug in an immediate-release form,” (Exhibit H, ’616 patent, 23:7-8), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

173. Osmotica’s Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent. Therefore, any use by third parties, including physicians and patients, of Osmotica’s Osmolex ER™ product in accordance with its approved product label will not satisfy the limitations of claim 1 of the ’616 patent.

174. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the ’616 patent.

COUNT VIII: DECLARATION OF NON-INFRINGEMENT OF THE ’617 PATENT

175. Osmotica expressly incorporates and realleges Paragraphs 1 through 174 above as if fully set out and stated herein.

176. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the ’617 patent.

177. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '617 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

178. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the '617 patent, either literally or under the doctrine of equivalents.

179. For example, claim 1 of the '617 patent, which is representative, is directed to a method comprising, *inter alia*, orally administering to a human subject a once-daily dose consisting of 200 mg to 500 mg of amantadine. *See* Exhibit I, '617 patent, 22:52-67. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the '617 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

180. Additionally, claim 1 of the '617 patent recites "a once-daily dose consisting of" amantadine or a pharmaceutically acceptable salt thereof and at least one excipient. Exhibit I, '617 patent, 22:56-58. Contextually, for example, when read in view of dependent claim 8 of the '617 patent, which requires that the dosage form "additionally comprises the drug in an immediate-release form," (Exhibit I, '617 patent, 24:9-10), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

181. Osmotica's Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent. Therefore, any use by third parties, including physicians and

patients, of Osmotica's Osmolex ER™ product in accordance with its approved product label will not satisfy the limitations of claim 1 of the '617 patent.

182. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '617 patent.

COUNT IX: DECLARATION OF NON-INFRINGEMENT OF THE '618 PATENT

183. Osmotica expressly incorporates and realleges Paragraphs 1 through 182 above as if fully set out and stated herein.

184. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '618 patent.

185. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '618 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

186. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe any valid and enforceable claim of the '618 patent, either literally or under the doctrine of equivalents.

187. For example, claim 1 of the '618 patent, which is representative, is directed to a dosage form consisting of 50 mg to 500 mg of amantadine or its salt, and at least one excipient, wherein the drug in the dosage form comprises an extended-release form, and wherein "the extended release form of the drug in the dosage form provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of the drug in an immediate release form, wherein the dC/dT values are measured in a single dose human pharmacokinetic study over the time period between 0 and 4

hours after administration." Exhibit J, '618 patent, 23:35-47. Contextually, for example, when read in view of dependent claim 10 of the '618 patent, which requires that the dosage form "additionally comprises the drug in an immediate-release form," (Exhibit J, '618 patent, 23:44), claim 1 is properly limited to dosage forms of amantadine that do not comprise an immediate-release component.

188. Osmotica's Osmolex ER™ product consists of an extended-release core surrounded by an immediate-release outer layer wherein both the core and the outer layer contain amantadine HCl as the active agent.

189. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not directly infringe any valid and enforceable claim of the '618 patent.

COUNT X: DECLARATION OF NON-INFRINGEMENT OF THE '333 PATENT

190. Osmotica expressly incorporates and realleges Paragraphs 1 through 189 above as if fully set out and stated herein.

191. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '333 patent.

192. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '333 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

193. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe any valid and enforceable claim of the '333 patent, either literally or under the doctrine of equivalents.

194. For example, claim 1 of the '333 patent, which is representative, requires an osmotic device comprising, *inter alia*, a core surrounded by a semipermeable membrane, and an

immediate-release overcoat, the core and the overcoat each comprises amantadine or a salt thereof, the device comprises a total amount of 50 mg to 500 mg of the drug, wherein following a single dose administration the device provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of the drug in an immediate-release form, measured between 0 and 4 hours after administration.

195. The dC/dT profile of Osmotica's Osmolex ER™ product after the administration of a single dose of Osmolex ER™ is greater than 40% of the dC/dT of the same quantity of an immediate-release form of amantadine HCl, measured between 0 to 4 hours after administration. Therefore, Osmotica's Osmolex ER™ product does not satisfy at least the following limitation recited in claim 1 of the '333 patent: "the osmotic device provides a mean change in amantadine plasma concentration as a function of time (dC/dT) that is less than 40% of the dC/dT provided by the same quantity of an immediate release form of the drug, wherein the dC/dT values are measured in a single dose human pharmacokinetic study over the time period between 0 and 4 hours after administration." Exhibit K, '333 patent, 23:21-40.

196. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not directly infringe any valid and enforceable claim of the '333 patent.

COUNT XI: DECLARATION OF NON-INFRINGEMENT OF THE '697 PATENT

197. Osmotica expressly incorporates and realleges Paragraphs 1 through 196 above as if fully set out and stated herein.

198. There is an actual, substantial, and continuing justiciable case or controversy between Osmotica and Adamas regarding infringement of the '697 patent.

199. Adamas's conduct has created reasonable apprehension that Adamas will file an action against Osmotica alleging infringement of the '697 patent, thereby impeding Osmotica's ability to launch its Osmolex ER™ product without a cloud of uncertainty.

200. The importation, manufacture, offer to sell, sale, and/or use of Osmotica's Osmolex ER™ product has not, does not, and will not directly infringe or induce or contribute to the infringement by others of any valid and enforceable claim of the '697 patent, either literally or under the doctrine of equivalents.

201. For example, claim 6 of the '697 patent, which is representative, is directed to a method comprising, *inter alia*, orally administering to a human subject a once-daily dose consisting of 200 mg to 500 mg of amantadine or a pharmaceutically acceptable salt thereof. Exhibit L, '697 patent, 24:20-23. Because Osmotica will not administer its Osmolex ER™ product to patients, Osmotica will not directly infringe the '697 patent. *See Warner-Lambert v. Apotex*, 316 F.3d 1348, 1363, n.7 (Fed. Cir. 2003).

202. Additionally, claim 6 further requires that at least 90% of the amantadine or a salt thereof in the dosage form is in an extended-release form. Exhibit L, '697 patent, 24:20-23.

203. Osmotica's Osmolex ER™ product consists of an immediate-release outer layer and an extended-release core, where the amount of amantadine HCl in the extended-release core is less than 90%. Therefore, any use by third parties, including physicians and patients, of Osmotica's Osmolex ER™ product in accordance with its approved product label will not satisfy at least the following limitations recited in claim 6 of the '697 patent: "wherein at least 90% of the drug in the composition is in an extended release form." Exhibit L, '697 patent, 24: 20-23.

204. Accordingly, Osmotica is entitled to a judicial declaration that Osmotica has not, does not, and will not infringe, directly or indirectly, the '697 patent.

PRAYER FOR RELIEF

WHEREFORE, Osmotica prays for a judgment that:

A. Declares that the commercial manufacture, use, offer for sale, sale and/or importation of Osmotica's Osmolex ER™ product has not, does not, and will not infringe any valid and enforceable claim of the patents-in-suit under 35 U.S.C. § 271(a)-(c) and/or (g);

B. Awards Osmotica its costs and attorneys' fees; and

C. Awards Osmotica such other and further relief as the Court may deem proper.

Dated: February 16, 2018

Respectfully submitted,

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